

Form PTO-1449

# INFORMATION DISCLOSURE CITATION IN AN APPLICATION

(Use several sheets if necessary)

Docket Number (Optional)  
3833.6USApplication Number  
To be assigned

Applicant Fallaux et al.

Filing Date October 23, 2001

Group Art Unit To be assigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
10	#4,405,712	09/20/83	Vande Woude et al.			
	#4,497,796	02/05/85	Salser et al.			
	#4,727,028	02/23/88	Santerre et al.			
	#4,740,463	04/26/88	Weinberg et al.			
	#5,190,931	03/02/93	Inouye			
	#5,208,149	05/04/93	Inouye			
	#5,378,618	01/03/95	Sternberg et al.			
	#5,518,913	05/21/96	Massie et al.			
	#5,545,522	08/13/96	Van Gelder et al.			

J1050 U.S. PTO  
10/038271  
10/23/01

## FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						YES	NO
10	#2,053,187	04/11/93	Canada				
	#WO 94/08026	04/14/94	PCT				
	#WO 94/11506	05/26/94	PCT				
	#WO 94/12649	06/09/94	PCT				
	#WO 94/23582	10/27/94	PCT				
	#WO 94/24297	10/27/94	PCT				
	#WO 94/26914	11/24/94	PCT				
	#WO 94/28152	12/08/94	PCT				
	#WO 94/28938	12/22/94	PCT				
	#WO 95/00655	01/05/95	PCT				
	#2 707 664	01/20/95	France				
	#WO 95/02697	01/26/95	PCT				
	#95201611.1	06/15/95	EP				

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

(2-92)

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior applications:

Serial No.: 09/333,820

Filed: June 15, 1999

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

Form PTO-1449

**INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION**  
*(Use several sheets if necessary)*

Docket Number (Optional)  
**3833.6US**

Application Number  
**T b assign d**

Applicant **Fallaux t al.**

Filing Date **10/23/2001**

Group Art Unit **To b assigned**
**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
<i>W</i>	#5,652,224	07/29/97	Wilson et al.			
	#5,670,488	09/23/97	Gregory et al.			
	#5,707,618	01/13/98	Armentano et al.			
	#5,753,500	05/19/98	Shenk et al.			
	#5,837,511	11/17/98	Falck-Pedersen et al.			
	#5,994,106	11/30/99	Kovesdi et al.			
	#5,994,128	11/30/99	Fallaux et al.			
	#6,033,908	03/07/2000	Bout et al.			
	#6,040,174	03/21/2000	Imler et al.			

**FOREIGN PATENT DOCUMENTS**

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						YES	NO
<i>W</i>	#WO 95/16772	06/22/95	PCT				
	#95201728.3	06/26/95	EP				
	#2,117,668	09/10/95	Canada				
	#WO 95/26411	10/05/95	PCT				
	#WO 95/27071	10/12/95	PCT				
	#WO 95/34671	12/21/95	PCT				
	#AU-A-28533/95	03/21/96	Australia				
	#WO 96/13596	05/09/96	PCT				
	#WO 96/14061	05/17/96	PCT				
	#WO 96/16676	06/06/96	PCT				
	#WO 96/18418	06/20/96	PCT				
	#WO 96/33280	10/24/96	PCT				
	#WO 96/40955	12/19/96	PCT				
	#WO 97/00947	01/09/97	PCT				
	#WO 97/04119	02/06/97	PCT				
	#WO 97/05255	02/13/97	PCT				

EXAMINER

DATE CONSIDERED

*9130/03*

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

(2-92)

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior applications:

Serial No.: 09/333,820

Filed: June 15, 1999

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

Form PTO-1449  <b>INFORMATION DISCLOSURE CITATION</b> <b>IN AN APPLICATION</b> <i>(Use several sheets if necessary)</i>	Docket Number (Optional) <b>3833.6US</b>	Application Number <b>To b assigned</b>
	Applicant <b>Fallaux t al.</b>	
	Filing Date <b>10/23/2001</b>	Group Art Unit <b>To b assign d</b>

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Examiner initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
		#Amalfitano et al., "Improved adenovirus packaging cell lines to support the growth of replication-defective gene-delivery vectors", <u>Proc. Natl. Acad. Sci. USA</u> , 93:3352-3356, April 1996.
		#Amalfitano et al., "Isolation and characterization of packaging cell lines that coexpress the adenovirus E1, DNA polymerase, and preterminal proteins: implications for gene therapy", <u>Gene Therapy</u> 4:258-263, 1997.
		#Armentano et al., "Characterization of an Adenovirus Gene Transfer Vector Containing an E4 Deletion", <u>Human Gene Therapy</u> , 6:1343-1353, October 1995.
		#Bernards, Rene, et al., "Characterization of Cells Transformed by Ad5/Ad12 Hybrid Early Region I Plasmids", <u>Virology</u> , 120:422-432, 1982.
		#Bernards, Rene, et al., "Role of Adenovirus Types 5 and 12 Early Region 1b Tumor Antigens in Oncogenic Transformation", <u>Virology</u> , 127:45-53, 1983.
		#Brough et al., "A Gene Transfer Vector-Cell Line System for Complete Functional Complementation of Adenovirus Early Regions E1 and E4", <u>Journal of Virology</u> 70(9):6497-6501, September 1996.
		#Brough et al., "Construction, Characterization, and Utilization of Cell Lines Which Inducibly Express the Adenovirus DNA-Binding Protein", <u>Virology</u> , 190:624-634, 1992.
		#Brough et al., "Multiple Functions of the Adenovirus DNA-Binding Protein Are Required for Efficient Viral DNA Synthesis", <u>Virology</u> , 196:269-281, 1993.
		#Brough et al., "Restricted changes in the adenovirus DNA-binding protein that lead to extended host range or temperature sensitive phenotypes", <u>Journal of Virology</u> , Vol. 55, pp. 206-212.
		#Brough et al., "Stable Cell Lines for Complementation of Adenovirus Early Regions E1, E2A and E4; Abstract Book CSH Conference On Gene Therapy, 42, 1996.
		#Caravokyri et al., "Constitutive Episomal Expression of Polypeptide IX (pIX) in a 293-Based Cell Line Complements the Deficiency of pIX Mutant Adenovirus Type 5", <u>Journal of Virology</u> 69(11):6627-6633, November 1995.
		#Engelhardt et al., "Ablation of E2A in recombinant adenoviruses improves transgene persistence and decreases inflammatory response in mouse liver", <u>Proceeding of the National Sciences of USA</u> Vol. 91, pp. 6196-6200, 1994.
		#Fallaux et al., "Characterization of 911: A New Helper Cell Line for the Titration and Propagation of Early Region 1-Deleted Adenoviral Vectors", <u>Human Gene Therapy</u> , 7:215-222, 1996.
		#Fields et al., "Fields Virology", Second Edition, pp. 28-30, 87.
		#Fisher et al., "Recombinant Adenovirus Deleted of All Viral Genes for Gene Therapy of Cystic Fibrosis", <u>Virology</u> , 217:11-22, 1996.
		#Gao et al., "Biology of Adenovirus Vectors with E1 and E4 Deletions for Liver-Directed Gene Therapy", <u>Journal of Virology</u> , 70(12):8934-8943, December 1996.

EXAMINER		DATE CONSIDERED	9/30/03
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.			

(2-92)

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior applications:

Serial No.: 09/333,820


Filed: June 15, 1999

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

Form PTO-1449

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION  
(Use several sheets if necessary)Docket Number (Optional)  
**3833.6US**Application Number  
**To be assigned**Applicant **Fallaux et al.**Filing Date **10/23/2001**Group Art Unit **To be assigned**

## OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
		#Gorziglia et al., "Elimination of both E1 and E2a from Adenovirus Vectors Further Improves Prospects for In Vivo Human Gene Therapy", <u>Journal of Virology</u> , 70(6):4173-4178, June 1996.
		#Graham, F.L., et al., "Characteristics of a Human Cell Line Transformed by DNA from Human Adenovirus Type 5", <u>J. gen. Virol.</u> , 36:59-74, 1977.
		#Grodzicker, Terri, et al., "Expression of Unselected Adenovirus Genes in Human Cells Co-transformed with the HSV-1 tk Gene and Adenovirus 2 DNA", <u>Cell</u> , 21:453-463, September 1980.
		#Hardy et al., "Construction of Adenovirus Vectors through Cre-lox Recombination", <u>Journal of Virology</u> 71(3):1842-1849, March 1997.
		#Hehir et al., "Molecular Characterization of Replication-Competent Variants of Adenovirus Vectors and Genome Modifications To Prevent Their Occurrence", <u>Journal of Virology</u> , 70(12):8459-8467, December 1996.
		#Imler et al., "Novel complementation cell lines derived from human lung carcinoma A549 cells support the growth of E1-deleted adenovirus vectors", <u>Gene Therapy</u> , 3:75-84, 1996.
		#Kornberg, Arthur, "DNA Replication", W.H. Freeman and Company, San Francisco, 4 pages (double sided).
		#Krougliak et al., "Development of Cell Lines Capable of Complementation E1, E4, and Protein IX Defective Adenovirus Type 5 Mutants", <u>Human Gene Therapy</u> , 6:1575-1586, December 1995.
		#Lemarchand et al., "Adenovirus-mediated transfer of a recombinant human $\alpha$ 1-antitrypsin cDNA to human endothelial cells", <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 89, pp. 6482-6486, July 1992.
		#Lieber et al., "Recombinant Adenoviruses with Large Deletions Generated by Cre-Mediated Excision Exhibit Different Biological Properties Compared with First-Generation Vectors In Vitro and In Vivo", <u>Journal of Virology</u> , 70:8944-8960, December 1996.
		#Lochmuller, H., et al., "Emergence of Early Region 1-Containing Replication-Competent Adenovirus in Stocks of Replication-Defective Adenovirus Recombinants ( $\Delta$ E1 + $\Delta$ E3) During Multiple Passages in 293 Cells", <u>Human Gene Therapy</u> , 5:1485-1491, December 1994.
		#Louis, Nathalie, et al., "Cloning and Sequencing of the Cellular-Viral Junctions from the Human Adenovirus Type 5 Transformed 293 Cell Line", <u>Virology</u> , 233:423-429, 1997.
		#Ngo et al., "in The Protein Folding Problem and Tertiary Structure Prediction", Merz et al., (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, 1994.
		#Orkin et al., "Reports and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy", 21 pages, December 7, 1995.
		#Roberts, Bryan E., et al., "Individual Adenovirus Type 5 Early Region 1A Gene Products Elicit Distinct Alterations of Cellular Morphology and Gene Expression", <u>Journal of Virology</u> pp. 404-413, Nov. 1985.
		#Rosenfeld et al., "In Vivo Transfer of the Human Cystic Fibrosis Transmembrane Conductance Regulator Gene to the Airway Epithelium", <u>Cell</u> , Vol. 68, pp. 143-155, January 10, 1992.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

(2-92)

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior applications:











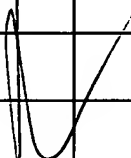
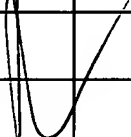
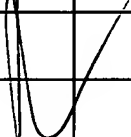
Serial No.: 09/333,820

Filed: June 15, 1999

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

Form PTO-1449

**INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION**  
*(Use several sheets if necessary)*
Docket Number (Optional)  
**3833.6US**Application Number  
**To b assign d**Applicant **Fallaux t al.**Filing Date **10/23/2001**Group Art Unit **To b assigned****OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
		#Sabatie et al., "Process Development for the Production of Second Generation Adenovirus Vectors for Gene Transfer in Clinical Protocols", <u>Abstract Book 14th Meeting on Animal Cell Technology</u> BI-3, 1996.
		#Schaack et al., "Adenovirus Type 5 Precursor Terminal Protein-Expressing 293 and HeLa Cell Lines", <u>Journal of Virology</u> , 69(7):4079-4085, July 1995.
		#Stratford-Perricaudet, Leslie, et al., "Gene Transfer Into Animals: The Promise of Adenovirus, Human Gene Transfer", 219:51-61, 1991.
		#Trapnell et al., "Gene therapy using adenoviral vectors", <u>Current Opinion in Biotechnology</u> 5:617-625, 1994.
		#Vaessen, R.T.M.J., "Adenovirus E1A-Mediated Regulation of Class I MHC Expression", <u>The EMBO Journal</u> , 5(2):335-341, 1986.
		#Vaessen, R.T.M.J., "Different Adenovirus E1A-Controlled Properties of Transformed Cells Require Different Levels of E1A Expression", <u>Gene</u> , pp. 247-254, 1987.
		#Vanhaesebroeck, Bart, et al., "Modulation of Cellular Susceptibility to the Cytotoxic/Cytostatic Action of Tumor Necrosis Factor by Adenovirus E1 Gene Expression Is Cell Type-Dependent", <u>Virology</u> 176:362-368, 1990.
		#Vos et al., "Characterization of Adenovirus Type 5 Insertion and Deletion Mutants Encoding Altered DNA Binding Proteins", <u>Virology</u> , 172, pp. 634-642, 1989.
		#Wang et al., "A packaging cell line for propagation of recombinant adenovirus vectors containing two lethal gene-region deletions", <u>Gene Therapy</u> , 2:775-783, 1995.
		#Weinberg et al., "A cell line that supports the growth of a defective early region 4 deletion mutant of human adenovirus type 2", <u>Proc. Natl. Sci. USA</u> , Vol. 80, pp. 5383-5386, September 1983.
		#Yang et al., "Cellular immunity to viral antigens limits E1-deleted adenoviruses for gene therapy", <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 91, pp. 4407-4411, May 1994.
		#Yeh et al., "Efficient Dual Transcomplementation of Adenovirus E1 and E4 Regions from a 293-Derived Cell Line Expressing a Minimal E4 Functional Unit", <u>Journal of Virology</u> , 70(1):559-565, January 1996.
		#Zhou et al., "Development of a Complementing Cell Line and a System for Construction of Adenovirus Vectors with E1 and E2a Deleted", <u>Journal of Virology</u> , 70(1):7030-7038, October 1996.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

(2-92)

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior applications:

Serial No.: 09/333,820

Filed: June 15, 1999

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.